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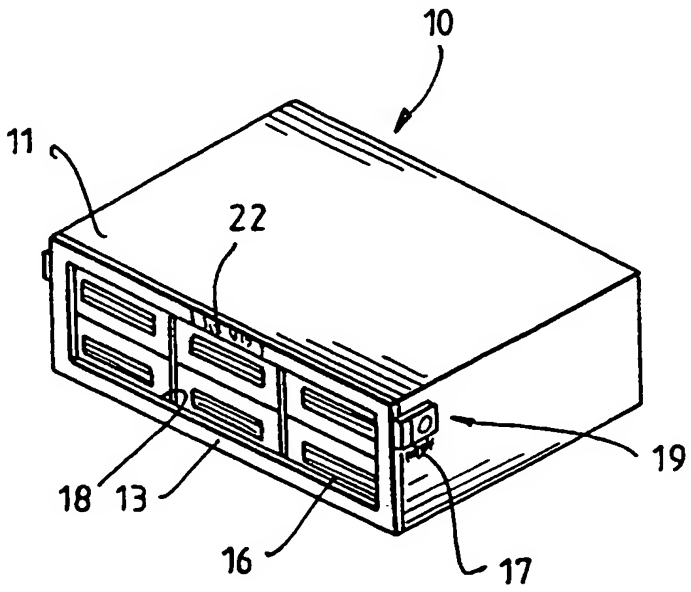
(54) Title: CONSIGNMENT MEDICAL KIT HANDLING SYSTEM



(57) Abstract: A method of kit handling of a range of medical devices, the kit consisting of at least one transportable module, comprising grouping a range of medical devices and packing the grouped devices in the module as contents of the module; sealing the module with a seal; and providing the exterior of the module with a coded identification means that identifies each device in the module such that, as long as the seal is intact, the contents of the module can be assessed externally of the module by reading only the identification means.

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CONSIGNMENT MEDICAL KIT HANDLING SYSTEM

FIELD OF THE INVENTION

The present invention relates to an improved system of handling or processing kits between a supplier and a customer, and in particular processing of loan and consignment medical kits.

BACKGROUND OF THE INVENTION

Certain surgical procedures in medicine require the surgeon to have on hand a range of products, or medical devices, for immediate selection of one product to use in the procedure. Examples of such products are implants and disposable instruments. Often, the surgeon does not know until a few hours before the procedure, or while in the operating theatre, exactly what type or size of implant or instrument will be needed. At this stage it is too late to order the correct product from the supplier. This has led to the common practice of suppliers supplying hospitals and other medical institutions with a range of similar devices as loan kits or consignment kits.

Consignment kit processing involves the supply to hospitals, etc., of a product in a variety of sizes and types. For example, different sizes of left femoral hip implants may be delivered to a hospital for the surgeon, while in the operating theatre, to choose the implant of best fit for the patient. The products are individually packed and sealed, and delivered in tubs, cartons, cases, or the like. Before surgery, nursing staff arrange the products in order of size, type, etc, so that the particular product chosen by the surgeon is easily and quickly accessible.

It is not always desirable for hospitals to purchase an

entire range of a product as some products in the range are more popular than others and not all products in the range will necessarily be used over time. This has brought about loan kit processing between hospitals and suppliers. This involves the delivery of a kit, that is, a product range, to the hospital which is specifically ordered for a scheduled procedure. The nursing staff lay out the products in a logical order and the product selected by the surgeon is easily and quickly accessed. Any products not used during surgery are returned to the supplier and the hospital only pays for the products used.

For inventory purposes, the supplier must account for all out-going products and, in the case of loan kit processing, for all in-coming products. Account is taken of all products by scanning into a computer inventory database the bar codes provided on each packed product. Where bar codes are not used, the product identification means particular to the system is entered onto the database, whether it be manual identification or another form of computerised identification. Information imparted by the product identification means relates to such information as product catalogue number and lot number. In this way an accurate assessment is available of all products in the supplier's warehouse as well as what products have been delivered. Further, for loan kit processing, the supplier can quickly determine what products were used by the hospital by simply deducting the scanned in-coming products from the corresponding scanned out-going products.

As an example of a typical loan kit process, an orthopaedic implant or disposable instrument is usually packed in a sterile, sealed container, sterilised and sealed. Picking an order and preparing a kit of a range of orthopaedic implants involves scanning different sizes and types of the packed implants twice, placing the them

in a container such as a plastic tub, cardboard carton, or the like, and delivering the kit to the hospital. Once at the hospital, the nursing staff unpacks the packed products from the tub, checks them against a checklist and stacks them in a logical order on a bench or on a hospital trolley. When the surgeon requires a particular type/size of implant, the nursing staff approaches the piles of products, selects the implant, confirms the implant's identity with the surgeon and then removes it from its package and hands it to the surgeon. After the surgical procedure the unused products are loaded back into the tub in random order and delivered back to the supplier.

On return of the tub, each in-coming packed product is scanned twice and stacked back into the supplier's warehouse.

The whole loan and consignment kit process, and in particular the loan kit process, requires considerable time in scanning each individual product on despatch as well as all unused products on return. Generally, the majority of products in a tub or carton are unused and returned. In some cases the tubs are returned completely unused due to cancellation of the surgical procedure, or some other reason. In these cases, much time is wasted in scanning tubs full of returned products none of which are even used. More time is wasted by the supplier in removing the products from the tubs and arranging them in ordered stacks in the warehouse.

In addition to the time consumed by the supplier in scanning each returned product, time is consumed by the nursing staff in removing the products from the tubs and arranging them in ordered stacks. All products need to be removed from the tub and checked against the supplier's checklist to ensure all the products ordered are present. There is further a problem with stacking the products in

that multiple rows of packed products balanced on a trolley can become unstable and topple.

An improved system for processing kits is therefore needed to increase system efficiency and maximise convenience for the supplier and for the customer.

SUMMARY OF THE INVENTION

According to the present invention there is provided a method of kit handling of a range of medical devices, the kit consisting of at least one transportable module, comprising:

grouping a range of medical devices and packing the grouped devices in the module as contents of the module;

sealing the module with a seal; and

providing the exterior of the module with a coded identification means that identifies each device in the module such that, as long as the seal is intact, the contents of the module can be assessed externally of the module by reading only the identification means.

The method further preferably comprises validating the module for inventory control if the seal is unbroken or validating each product inside the module for inventory control if the seal is broken.

The method preferably comprises providing information on the module in the form of a barcode and further guaranteeing the contents of the module by visually identifying the contents through a transparent window on the module.

Preferably, the method comprises filling voids in the module between products, and between products and internal walls of the module, with blanks.

The method further preferably comprises loading one or more modules into a wheel-based case and delivering the case to a customer.

According to the present invention there is further provided a method of supplying a range of medical devices by way of a loan kit, the kit consisting of at least one transportable module, the method comprising;

grouping a range of devices and packing the grouped devices into the module as contents of the module;

sealing the module with a seal;

providing the exterior of the module with a coded identification means that identifies each device in the module such that, as long as the seal is intact, the contents of the module can be assessed externally of the module by reading only the identification means;

reading the identification means on the module in the kit for the purposes of inventory control;

forwarding the kit to a user;

receiving the kit from the user and validating the returned kit for the purposes of inventory control by reading the identification means on the module if the seal is intact, or noting the identity of each device in the module if the seal is broken.

BRIEF DESCRIPTION OF THE DRAWINGS

An embodiment, incorporating all aspects of the invention, will now be described by way of example only with reference to the accompanying drawings in which:

Figures A1 and A2 are a schematic representation of a prior art system of kit handling;

Figure 1 illustrates an empty module of the present invention and product to fill the module;

Figure 2 is a perspective view of a filled module;

Figure 3 is a front view of a first filled module;

Figure 4 is a front view of a second filled module;

Figures 5A and 5B are a schematic representation of a system of kit handling according to the present invention; and

Figure 6 is a perspective view of modules loaded in a transport case.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENT

The present invention concerns an efficient and convenient system of loan and consignment kit handling. Specific reference will be made to the kit handling of orthopaedic implants although it is understood that the system is equally applicable to any kind of medical device including other implants, disposable medical instruments, medical supplies, diagnostic kits or any other medical equipment which is generally package sterile or unsterile and supplied by loan or consignment kit systems.

In particular, the present system is based on delivering kits in sealed modules, the kits comprising a range of pre-packed implants. A typical module 10 is illustrated in figure 1 and comprises a rectangular corrugated plastic container 11 and a hinged opening panel 12 at a front end. It is understood that the whole or part of the module may be made from materials other than plastics, such as cardboard or metal. The module 10 is packed with sealed implant packs 15. The specific module 10 illustrated in figure 1 is designed to receive six implant packs 15, which are loaded into the module. The packs are arranged

in the modules so that a product information label 16 on each implant pack 15 can be viewed through a window 18 provided on the panel 12. Thus, when panel 12 is closed as shown in figure 2, the implant packs and labels are visible through window 18.

The module is provided with a latch 19 comprising detents 20 fixed onto sides of the frame 13 of the panel, and corresponding receiving means 21 on the module container 11. On closing panel 12 onto the container 11, detents 20 click into receiving means 21. The latch is sealed with a seal 17 which can be an adhesive strip or a breakable plastic tie. In the preferred embodiment, the latch is sealed using a bar code sticker. The seal 17 must be broken in order to open the module.

A module identification label 22 is provided on the exterior of the module on the panel frame. By sealing the module, the provider of the module (for example, manufacturer or distributor) brings integrity to the module guaranteeing that the products, or devices, identified by the module identification label 22 are the actual products, or devices, inside the module. The identification label may be a reference identification number or a bar code. Further, validation of the contents is visually possible through window 18 in panel 12. Integrity and guarantee of product is important for the customer because the module does not need to be opened and its contents checked before a surgical procedure. This reduces preparation time for hospital staff but also reduces scanning time for the supplier if the module is returned. If the seal is not broken, the supplier need only scan the module and not it's contents because the guarantee remains that the products inside the module are those identified by the module label.

In one preferred embodiment, the identification label is a

bar code on the exterior of the module. At the time of packing the module, the contents of the module are noted, recorded on a database and assigned an unique reference code that is printed in the form of an adhesive bar code. The bar code is adhered to the exterior of the module. The information contained on the bar code, that is a list of the module's contents, is read by simply scanning with a bar code reader. In another embodiment, an unique reference number on the module is assigned to the list of products contained in the module. A master list of reference numbers is consulted to identify the contents of the module.

The modules are designed to carry implant packs of different shapes and sizes. To avoid movement during transportation, the implant packs should be securely packed against each other but not so as to cause damage to the packs. The individual implant packs should be easily removable. Since the modules are designed to carry implant packs of different shapes and sizes it is not always possible to pack implants in a manner that eliminates all voids. Further, the packs should be brought to the front of the module so that the product labels 16 on each pack 15 face the front panel 12 and are clearly visible through window 18. In order to achieve compact packing, blanks 24 made of wire cut poly armcel are used to fill voids in the packed module as illustrated in figure 1. Of course, blanks from other suitable materials can be used as void fillers. Small packs 15, such as those illustrated in figure 1, are packed at the front of the module with blanks filling the void at the rear interior of the module. If longer implant packs are loaded into the module, the blanks are removed to accommodate the extra length of the pack. Dividers 25 are inserted between vertical rows of packs to maintain alignment and to provide the module with extra strength against damage during transporting and stacking when the

module is empty.

Figures 3 and 4 illustrate two differently sized modules. The module illustrated in figure 4 is designed to accommodate a greater number of products than the module illustrated in figure 3. Voids in the modules are filled with space fillers, specifically blanks 24, which ensure products in the modules will not displace during transportation.

Loan and consignment kit handling systems require the supplier to validate or scan all products into an inventory database before despatch. In the case of loan kit systems, all products are also validated (that is, by scanning or manual validation) by the supplier on return of the kits. Accurate account can therefore be taken of all products despatched and all products returned. In the case of loan kit systems, the supplier can determine what products were used by the hospital by noting the discrepancies between the products despatched and products returned in a particular order.

Figure A1 schematically illustrates an example of a prior art system of kit implant despatch. Columns 1, 2 and 3 represent groups of three different implant products. Group 1 comprises five products, group 2 comprises four products, and group 3 comprises three products. Each product has two bar code labels identifying catalogue number and lot number which must each be scanned during despatch of an order. Therefore, the total number of bar codes scanned in groups 1, 2 and 3 at despatch are twenty four. In the case of loan kit handling, the products are returned randomly placed in a tub and two labels on all the products are scanned to determine which products were actually used. Figure A2 schematically illustrates an incoming loan kit wherein one product from group 3 was used by the hospital. Group 1 still comprises five products,

group 2 comprises four and group 3 now comprises two products. With two bar codes on every product, a total of twenty two bar codes are scanned into the inventory database upon return. The total number of times bar codes scanned over the course of despatch and return is, therefore, forty six. Scanning bar codes and re-sorting the products is time consuming, inefficient and imposing on the warehouse staff.

Figures 5A and 5B illustrate the present improved system of loan and consignment kit handling using modules. In the present system, the products in groups 1, 2 and 3 illustrated in figure A1 are packed and sealed in group modules. Therefore, module 1 in figure 5A contains five products, module 2 contains four products and module 3 contains three products. The modules are provided with only one bar code for scanning. The bar code represents the "bill of materials" and provides information on the contents of the module which is unique for every module. Only three bar codes are scanned at despatch, one for each module. This provides a significant reduction of bar codes scanned from the twenty four bar codes scanned with typical systems of loan and consignment kit handling. With respect to loan kit handling systems, hospital staff may only partially use a kit order by taking, as in the previous prior art example, only one product from group 3. This is illustrated in figure 5B. In reality, the hospital staff would arrange the kit order, comprising three modules of different products, on a bench surface or a trolley. The modules are delivered from the supplier sealed and the seal is only broken if a specific product in that module is required by the surgeon.

Products inside the modules are identifiable as they can be seen through the transparent window at the front of the module. Products are further validated and confirmed by the information contained on the module bar code. The

sealed modules save time for hospital staff in that there is no need for hospital staff to check individual products to ensure all the correct products were delivered.

Referring back to the situation in figure 5B, no products from modules 1 and 2 were used, however one product from module 3 was used. Once the seal on module 3 is broken, the module loses its integrity, that is, the guarantee provided by the supplier as to what is contained in the module. One product is removed from module 3 and two remain. The whole order comprising modules 1, 2 and 3 is returned to the supplier who invoices the hospital only for the products actually used. Modules 1 and 2 are returned intact and still integrity sealed. There is thus no need for the supplier to check individual products inside modules 1 and 2 to ensure all are present. Only one bar code on each of modules 1 and 2 is scanned into the inventory database, whilst the two remaining products in module 3 are individually scanned (both labels on each product are scanned) since the integrity of module 3 was destroyed when the seal was broken. The total number of bar codes scanned on the in-coming kit is six, one for each modules 1 and 2 and two bar codes for each of the two products remaining in module 3. Over the entire despatch and return process of the present system, bar codes are scanned a total of nine times. In comparison to the forty six times the codes are scanned with a typical loan kit handling system as described above, the merits of the present system are obvious. The reduction in scanning time is especially noticeable with despatch and return of large numbers of kit orders.

A kit of modules is delivered in a transport case 26 as illustrated in figure 6. The transport case is essentially a large plastic container with a hinged lid 27 and also includes a detachable trolley 28 on which the case is wheeled along the ground. The modules 10 are

vertically loaded into the case and empty spaces 29 between the modules and the interior of the case provide pockets for templates and information packs. The modules 10 and/or case 26 may have handles (not shown) to assist in lifting and transportation.

The present system of packing and sealing groups of like implants in tamper evident modules provides benefits to the supplier of the product and to the customer. Specifically referring to the benefits to the supplier, the present system reduces despatch time in loan and consignment kit handling by reducing the time for scanning and sorting of the products. This results in faster booking-delivery turnaround and less pressure to deliver a late booking. On return of kits using loan kit handling, the time spent at inwards receiving is reduced as is the time spent in re-stacking the individual implants in the warehouse. Rather, the implants are packed in modules which are themselves stacked on warehouse shelves ready to be picked for the next kit order.

The present kit handling system promotes increased efficiency of warehouse stocktakes and the system provides ergonomic improvements to the warehouse environment.

With some loan kits returned completely unused, in a typical loan kit handling system each and every product in the kit would be sorted and scanned twice at despatch and sorted and scanned twice at inwards. With the present system the modules are scanned at despatch and only products in a used module are individually scanned at inwards receiving. The overall processing time saved is dramatic.

Benefits to the customer, that is hospitals, surgicentres and the like, include increased efficiency in sorting and preparing for a surgical procedure and time saved in re-

packing after the procedure. The present system is convenient to use and ergonomically friendly for hospital staff as there is no need for unpacking or precarious stacking of individual implant packs. There is additionally no need for sorting the packs as they are already sorted within the modules. The security seal validates the contents of the module, thus there is no need for hospital staff to check individual implants as is the case with prior art systems. It is only the individual modules that are checked against an order form. When a used module is returned to the supplier, the module is refilled with the appropriate implant pack and sealed to create a new bill of materials.

It will be understood to persons skilled in the art of the invention that many modifications may be made without departing from the spirit and scope of the invention. For example, the clear window in the front panel of the module may be replaced by an opaque panel provided with identity stickers which correspond to and identify the products within the module.

For the purposes of this specification it will be clearly understood that the word "comprising" means "including but not limited to", and that the word "comprises" has a corresponding meaning.

CLAIMS:

1. A method of kit handling of a range of medical devices, the kit consisting of at least one transportable module, comprising:

grouping a range of medical devices and packing the grouped devices in the module as contents of the module;

sealing the module with a seal; and

providing the exterior of the module with a coded identification means that identifies each device in the module such that, as long as the seal is intact, the contents of the module can be assessed externally of the module by reading only the identification means.

2. The method according to claim 1 characterised by reading the identification means on the module for inventory control, forwarding the module to a product user, receiving the module from the user, and ,for the purposes of inventory control, reading the identification means on the module if the seal is intact, or noting the identity of each product inside the module if the seal is broken.

3. The method according to claims 1 or 2 characterised by at the time of packing the grouped devices, assigning the grouped devices an identification code or number and providing the code or number on the module as the identification means.

4. The method according to claim 3 characterised by providing the identification code or number in the form of a barcode.

5. The method according to claim 4 characterised by reading the identification means on the module by scanning the barcode onto a database.

6. The method according to any one of the preceding claims characterised by providing a single coded identification means.

7. The method according to any one of the preceding claims characterised by validating the contents of the module by visually identifying the contents through a transparent window on the module.

8. The method according to any one of the preceding claims characterised by filling voids in the packed module with space fillers.

9. A method of supplying a range of medical devices by way of a loan kit, the kit consisting of at least one transportable module, the method comprising;

grouping a range of devices and packing the grouped devices into the module as contents of the module;

sealing the module with a seal;

providing the exterior of the module with a coded identification means that identifies each device in the module such that, as long as the seal is intact, the contents of the module can be assessed externally of the module by reading only the identification means;

reading the identification means on the module in the kit for the purposes of inventory control;

forwarding the kit to a user;

receiving the kit from the user and validating the returned kit for the purposes of inventory control by reading the identification means on the module if the seal is intact, or noting the identity of each device in the module if the seal is broken.

10. The method according to claim 9 characterised by at the time of packing the grouped devices, assigning the grouped devices an identification code or number and

providing the code or number on the module as the identification means.

11. The method according to claim 12 characterised by providing the identification code or number in the form of a barcode.

12. The method according to claim 11 characterised by reading the identification means on the module by scanning the barcode onto a database.

13. The method according to any one of claims 9 to 12 characterised by providing a single coded identification means.

14. The method according to any one of claims 9 to 13 characterised by validating the contents of the module by visually identifying the contents through a transparent window on the module.

15. The method according to any one of claims 9 to 14 characterised by filling voids in the packed module with space fillers.

16. The method according to any one of claims 9 to 15 characterised by providing implants as the medical devices.

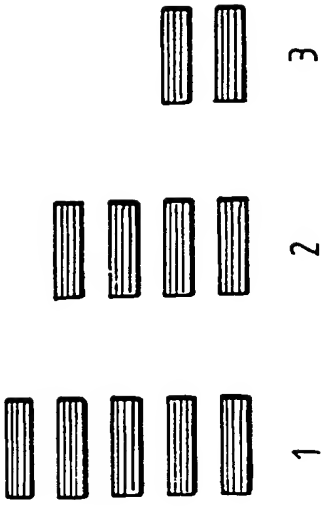

FIG. A2.

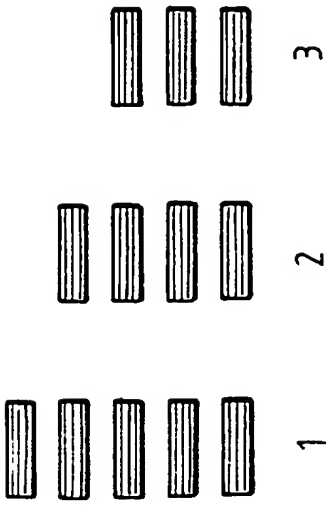

FIG. A1.

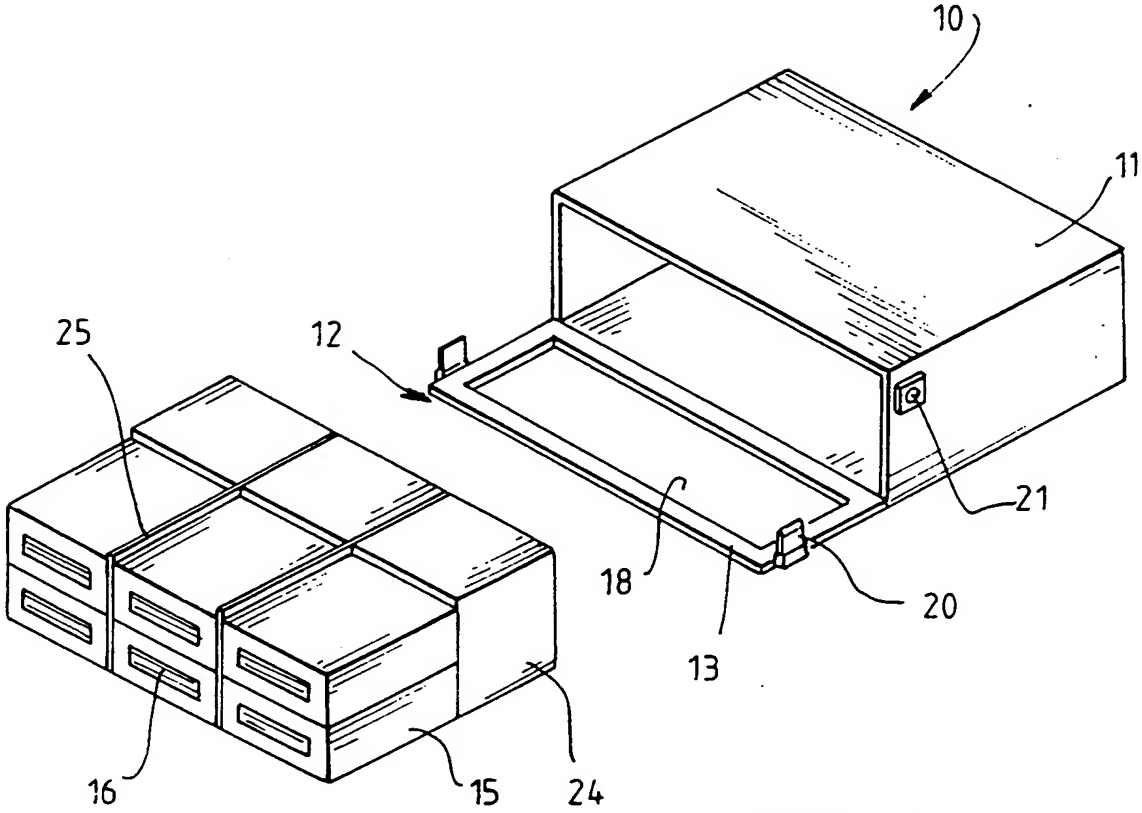

FIG. 1.

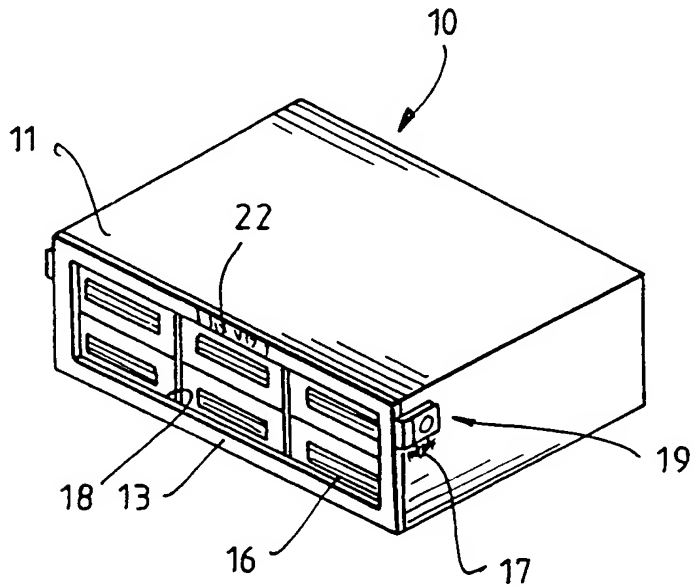

FIG. 2.

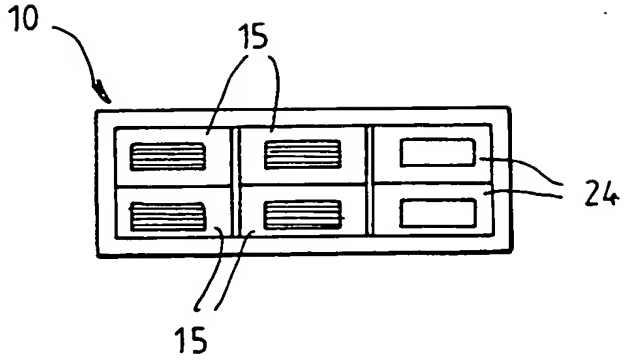

FIG. 3.

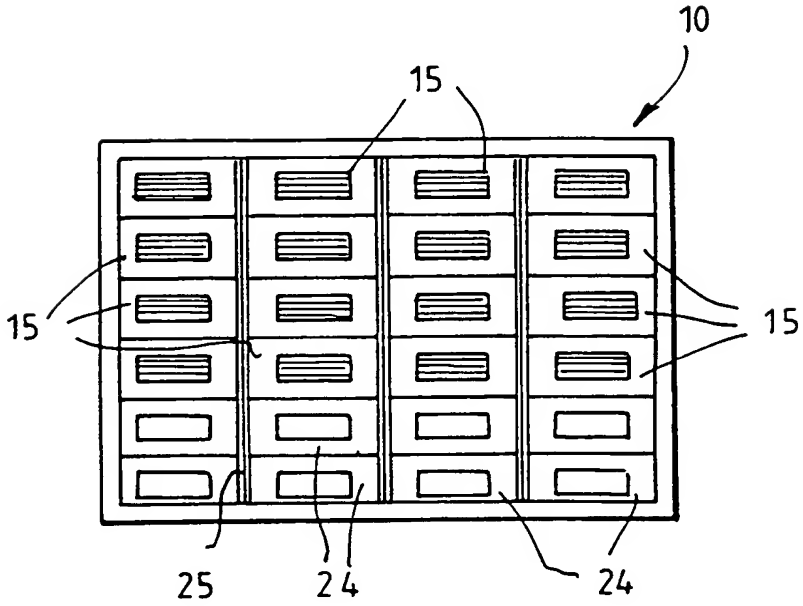

FIG. 4.

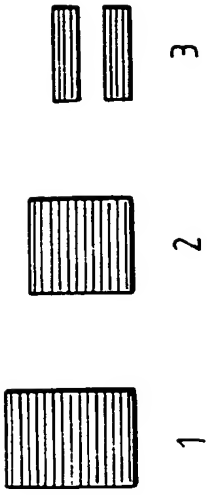

FIG. 5B.

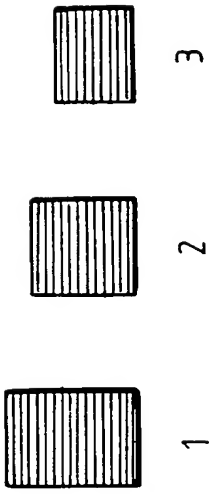

FIG. 5A.

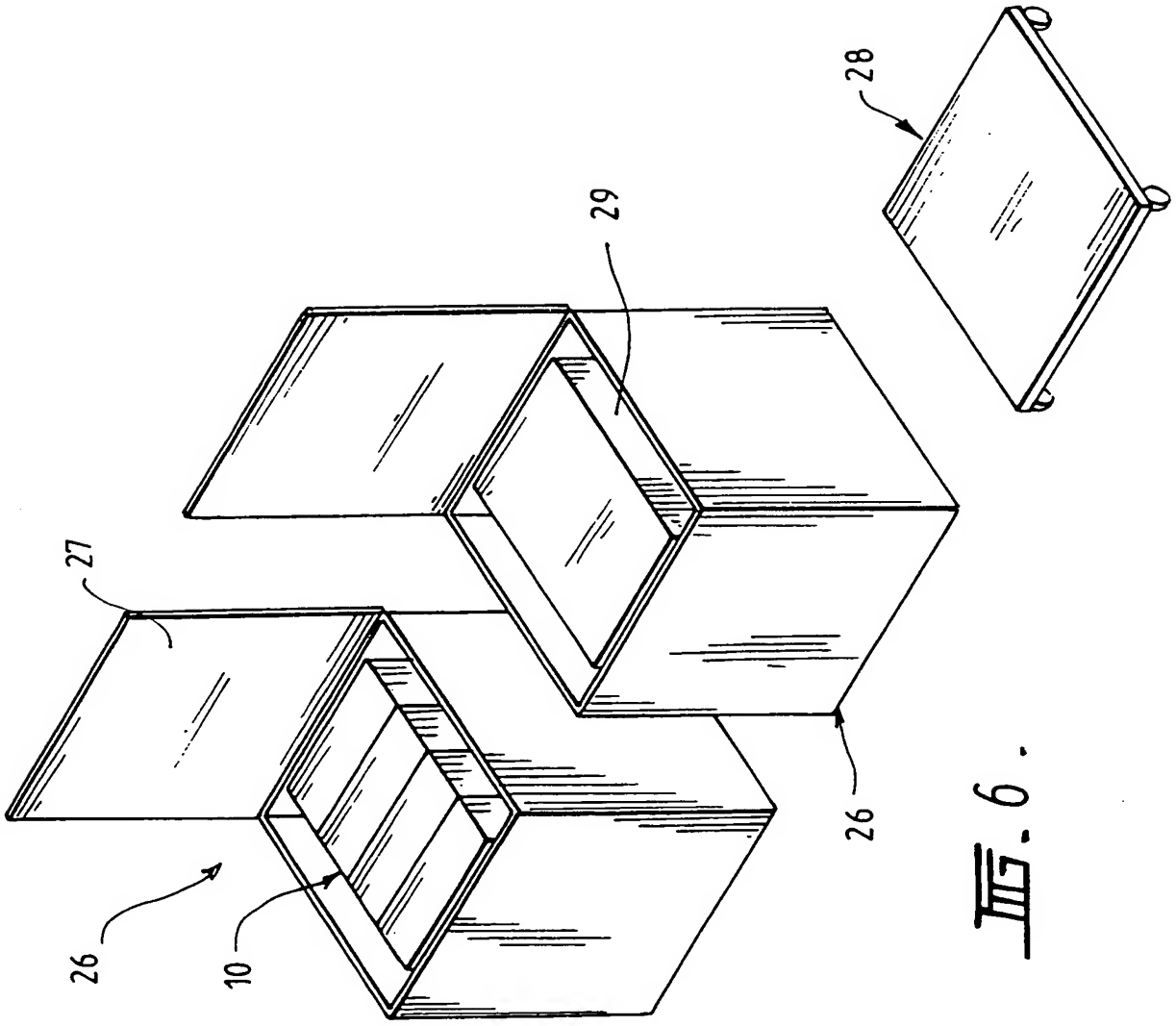

FIG. 6.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU01/00058

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. [7]: A61B 19/02, B65B 61/26

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC A61B 19/02, A61F 2/-, B65B 61/26, B65D 79/-

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
AU: IPC A61F 1/18

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
DWPI and keywords: see supplemental sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 4420707 A (C. STIEFENHOFER GmbH) 15 December 1994 See whole document. Monitoring and control of sterile products in modules using documentation process based on barcode identification. Derwent Abstract, Accession No. 97-290949/27, Classes Q31, Q35	1-16
A	DE 29705944 U (LEIBINGER MEDIZINTECHNIK KARL) 28 May 1997 See abstract. Prosthesis storage module with contents identification.	1-16
A	US 5979643 A (BLONDER et al) 9 November 1999 See whole document. Prosthesis storage module with visual contents.	1-16

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INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.
PCT/AU01/00058

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member			
DE	4420707	CZ	9401442	EP	630820
US	5979647	US	5934493		

END OF ANNEX